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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| Applicant(s): | SPRUIELL | Examiner: | MENDOZA, MICHAEL G |
| Serial No.: | 10/075,088 | Art Unit: | 3761 |
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Title: PATIENT USABLE EMERGENCY MEDICAL KIT

**APPELLANT'S BRIEF UNDER 37 C.F.R. § 1.192**

Commissioner of
Patents and Trademarks
Washington, D.C. 20231



Sir:

In compliance with 37 C.F.R. § 1.192 this Appeal Brief is being filed within two months of the date of the Notice of Appeal, mailed on 9/24/03 and received at the USPTO on 9/29/03. An authorized credit card payment form is filed herewith for $165.00 in accordance the fee 37 C.F.R. § 1.17 (c). This brief is filed in triplicate.

A CREDIT CARD PAYMENT FORM in the amount of $165.00 is enclosed herein.

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Name: Edward L. Kelley Signature: Edward L. Kelley Date: November, 28, 2003
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**1) REAL PARTY IN INTEREST:** Applicant Graham L. Spruiell M.D. is the only party in interest.

**2) RELATED APPEALS AND INTERFERENCES:** There are no related appeals or interferences.

**3) STATUS OF THE CLAIMS:**

Claims 2- 17, 19, 21, 22 and 25 - 34 are pending in the Application.

Claims 1, 18, 20 and 23 - 24 are cancelled.

None of the claims is allowed.

Claims 2 - 17, 19, 21, 22 and 25 - 34 are finally rejected and on appeal.

**4) STATUS OF THE AMENDMENTS**: No amendments have been submitted in response to the final rejection.

**5) SUMMARY OF THE INVENTION**

The invention provides a method and apparatus for treating an unexpected attack from a vascular disease, e.g. heart attack or stroke, by providing a portable emergency medical kit (10) to a person that is prone to, or may be at risk of an attack. The kit (10) includes a breathable oxygen delivery system (15) and one or more additional medications for providing any of the effects of reducing the tendency for blood clotting, reducing the need for oxygen, especially by vital organs, slowing the heart rate, maintaining a cardiac rhythm and or relaxing the arteries and veins, (Page 16, lines 5 - 25).

A physician may prescribe the kit (10) to the person at risk. The person may carry the kit (10) when traveling or keep the kit readily available in a home or vehicle, should an unexpected attack occur, (Page 16, line 28 - page 17, line 5). Immediate use of the kit (10), during the first hour after the onset of symptoms, (page 4, lines 17 - 20), may save the life of the person or reduce permanent tissue damage should an unexpected attack

occur, (Page 5, line 25 - 28). Use of the kit (10) does not require special training to operate or administer treatment, and the treatment may be self-administered, (Page 5, lines 18 - 20, page 8, line 27). The kit (10) requires no electrical devices or power of any kind; however, an electronic telephone or emergency signal generator may be included, (Page 17, lines 5 - 12). The kit (10) is housed in a portable bag or container (45) to protect the items contained in the kit, (Page 11, lines 18 - 28) and so that the kit (10) may be easily transported, or worn by the victim during use.

The breathable oxygen delivery system (15) comprises an oxygen tank or pressure vessel (20), a regulating valve (25), a facemask (35) and a hollow delivery tube (30) connected between the regulating valve and the facemask, (Page 7, lines 18 - 25). The regulator valve (25) is adjustable to provide desired flow rates to the user, usually in the range of about 3 to 8 liters per minute. In one example, the tank (20) supplies oxygen for a duration of about 40 minutes, (Page 10, line 18 - page 11 line 16). The oxygen flow rate may be preset according to a prescribed rate set by the physician.

Preferably the tank (20) is FDA approvable, refillable, has an internal volume of at least 50 cubic inches, has an empty weight in the range of about 1.5 - 5.0 pounds, and has a service pressure of up to 4000 pounds per square inch, (Page 9 line 26 through page 10 line 17 and page 11, line 15). In a preferred embodiment, the tank (20) comprises a composite material, e.g. carbon fibers, over wrapped onto a gas impermeable inner vessel; however, any lightweight tank construction meeting the basic requirements is usable with the kit (10).

Candidate medications for including within the kit (10) include one or more of an anticoagulant, such as acetylsalicyclic acid, clopidogrel, heparin and glycoprotein IIb/III/b inhibitors, an antiarrythmic agent, such as magnesium, or a cardioprotective agent, such as a beta blocker or an ACE inhibitor, (Page 13, line 5 - page 15, line 15). However, according to the invention, any medication, that when combined with breathable oxygen, aids in preventing thrombosis, assisting in inducing arteriolar relaxation, assisting in establishing a cardiac rhythm, and or assisting in diminishing oxygen demand, may be

prescribed by the physician and included in the kit with the breathable oxygen.

**6) ISSUES**

Whether claims 5, 7 and 14 - 16 are unpatentable under U.S.C. §102 (b) as being anticipated by Anderson 4197842.

Whether claims 2 - 4, 13, 17, 26 and 27are unpatentable under 35 U.S.C. 103(a) over Anderson in view of Mohan 4699288.

Whether claim 6 is unpatentable under 35 U.S.C. 103(a) over Anderson in view of Lowell et al. 6292687.

Whether claims 8-10, 11 and 29-32 are unpatentable under 35 U.S.C. 103(a) over Anderson in view of Zapol et al. 6063407.

Whether claims 12, 28, 29, 33 and 34 are unpatentable under 35 U.S.C. 103 (a) over Anderson in view of Duhaylongsod 6141589.

Whether claims 19, 21, 22 and 25 are unpatentable under 35 U.S.C. 103(a) over Zapol et al. in view of Kirchgeorge et al. 6327497.

**7) GROUPING OF THE CLAIMS**

Regarding the group of rejected claims 5, 7 and 14 - 16, rejected under U.S.C. §102 (b) as being anticipated by Anderson 4197842, claims 5 and 7 stand or fall together and claims 14 - 16 stand and fall together. However, claims 7 and 14 are separately patentable.

Claims 7 and 14 set out an emergency medical kit that includes a breathable oxygen delivery system and a medication. In claim 7, the medication is for use in response to symptoms of an attack of a vascular disease. In claim 14, the emergency medical kit is for use in a pre-hospital setting and the medication is for one of, assisting in preventing thrombosis, assisting in inducing arteriolar relaxation, assisting in establishing a cardiac rhythm, and, assisting in diminishing oxygen demand. Even if claim 7 is found to be anticipated, none of the prior art of record teaches or suggests an emergency

medical kit for use in a pre-hospital setting or an emergency medical kit that combines breathable oxygen with a medication for treating the symptoms set out in claim 14. Hence, claim 14 is patentably independent from claim 7.

Regarding the group of rejected claims, 2 - 4, 13, 17, 26 and 27, rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Mohan 4699288, claims 2-4 stand or fall together. However, claims 2, 13, 17, 26 and 27 are separately patentable.

Claims 2, 13, 17, 26 and 27 each set out an emergency medical kit that includes a medication for treatment of an attack of a vascular disease and an oxygen supply or tank. However, claim 2 includes the limitation, wherein the portable oxygen tank comprises a composite material, while claims 13, 17, 26 and 27 set out an oxygen tank having at least a 50 cubic inch internal storage capacity an oxygen storage operating pressure range of between 100 and 4000 PSI and an empty weight of less than 5.0 pounds. Even if claim 2 is found to be obvious, none of the prior art of record teaches or suggests an emergency medical kit having a medication for treating an attack of a vascular disease and an oxygen storage tank having at least a 50 cubic inch internal storage capacity an oxygen storage operating pressure range of between 100 and 4000 PSI and an empty weight of less than 5.0 pounds. Hence, claim 2 is patentably independent from claims 13, 17, 26 and 27.

In further distinctions, claim 2 includes the limitation that the medication is for use in response to symptoms of an attack of a vascular disease. Claim 13 includes the limitation that the medication is for use in response to symptoms of an attack of a vascular disease as soon as symptoms occur. Claim 17 includes the limitation that the medication is for one of assisting in preventing thrombosis; assisting in inducing arteriole relaxation; assisting in establishing a cardiac rhythm and assisting in diminishing oxygen demand. Claim 26 includes the limitation wherein the attack of a vascular disease comprises a heart attack. Claim 27 includes the limitation wherein the attack of a vascular disease comprises a stroke. Even if any one of claims 2, 13, 17, 26 and 27 is found to be obvious, none of the prior art of record teaches or suggests an emergency medical kit that includes a breathable oxygen supply and a medication defined by the

specific limitations set out in any of the other of claims 2, 13, 17, 26 and 27. Accordingly, each of the claims 2, 13, 17, 26 and 27 are patentably independent from each other.

Regarding the group of rejected claims 8-10, 11 and 29-32 rejected under 35 U.S.C. 103(a) over Anderson in view of Zapol et al., claims 10 and 29 stand or fall together and claims 9, 11 and 30 stand or fall together. However, claims 8, 9, 29, 31 and 32 are separately patentable.

Each of claims 8, 9, 29, 31 and 32 sets out an emergency medical kit having a breathable oxygen supply and a medication. However, claim 8 sets out that the medication is prescribed for a particular user by a physician and wherein the user has a known susceptibility to an attack of the vascular disease. Claim 9 sets out that the medication is an anticoagulant for use in response to symptoms of a particular serious illness as soon as the symptoms occur. Claim 29 sets out that the medication is a cardioprotective agent for use in response to symptoms of a particular serious illness as soon as the symptoms occur. Claim 31 sets out that the medication is provided in a dosage capable of preventing thrombosis. Claim 32 sets out that the medication is provided in a dosage capable of inducing arteriolar relaxation. Even if any one of claims 8, 9, 29, 31 and 32 is found to be obvious, none of the prior art of record teaches or suggests an emergency medical kit that includes a breathable oxygen supply and a medication defined by the specific limitations set out in any of the other of claims 8, 9, 29, 31 and 32. Accordingly, each of the claims 8, 9, 29, 31 and 32 are patentably independent from each other.

Regarding the group of rejected claims 12, 28, 29, 33, rejected under 35 U.S.C. 103 (a) over Anderson in view of Duhaylongsod, claims 12 and 28 stand or fall together. However, claims 28, 29 and 33 are separately patentable. Claims 28, 29 and 33 each set out an emergency medical kit that includes a breathable oxygen delivery system and a

medication. However, in claim 28 the medication is an antiarrythmic agent for use in response to symptoms of a particular serious illness as soon as the symptoms occur. In claim 29 the medication is a cardioprotective agent for use in response to symptoms of a particular serious illness as soon as the symptoms occur. In claim 33, the medication is provided in a dosage capable of establishing a cardiac rhythm. It is respectfully submitted that even if any one of the claims 28, 29 or 33 is found to be obvious, none of the prior art of record teaches or suggests an emergency medical kit that includes a breathable oxygen supply and a medication defined by the specific limitations set out in any of the other of claims 28, 29 and 33. Accordingly, each of the claims 28, 29 and 33 are patentably independent from each other.

Regarding the group of claims 19, 21, 22 and 25 rejected under 35 U.S.C. 103(a) over Zapol et al. in view of Kirchgeorge et al., each of the claims is separately patentable.

Claims 19, 21, 22 and 25 are each directed to a method for treating a serious attack of a vascular disease including the steps of providing a person with known susceptibility to the attack with a portable emergency medical kit that includes a supply of breathable oxygen. Claims 19 and 21 further include the steps of establishing a risk that the patient may suffer an unexpected attack of the vascular disease, predetermining a treatment for prolonging the patient's life, and reducing a risk of permanent tissue damage to the patient in the event that the attack occurs; and these limitations are not included in claims 22 and 25. Even if claims 22 or 25 are found to be obvious, none of the prior art of record teaches or suggests a method establishing a risk that the patient may suffer an unexpected attack of the vascular disease and predetermining a treatment for prolonging the patient's life and reducing a risk of permanent tissue damage to the patient in the event that the attack occurs.

In a further distinction, claims 21, 22 and 25 are separately patentable from claim 19 because they each include the limitation of treating a person susceptible to a serious attack of a vascular disease by providing the person with a breathable oxygen supply and

a medication for use in one of assisting in preventing thrombosis, assisting in inducing arterial relaxation, assisting in establishing a cardiac rhythm, and assisting in diminishing oxygen demand as soon as the symptoms of the serious attack occur. Hence, even if claim 19 is found to be obvious, none of the prior art of record teaches or suggests a method treating a person susceptible to a serious attack of a vascular disease by providing the person with a breathable oxygen supply and a medication for use in one of assisting in preventing thrombosis, assisting in inducing arterial relaxation, assisting in establishing a cardiac rhythm, and assisting in diminishing oxygen demand as soon as the symptoms of the serious attack occur.

In a still further distinction, claims 19, 21 and 25 are separately patentable from claim 22 because they each include the limitation of instructing or teaching a person in the use of breathable oxygen and the medication in response to predefined symptoms of the unexpected attack from the vascular disease. Hence even if claim 22 is found to be obvious, none of the prior art of record teaches or suggests a method instructing or teaching a person in the use of breathable oxygen and the medication in response to predefined symptoms of the unexpected attack from the vascular disease. Accordingly, each of the claims 19, 21, 22 and 25 are patentably independent from each other.

**8) ARGUMENT**

Claims 5, 7 and 14 - 16 are rejected under 35 U.S.C. §102 (b) as being anticipated by Anderson 4197842. Claims 5 and 7 stand or fall together. Claims 14 -16 stand or fall together.

The Examiner alleges; "Anderson teaches an emergency medical kit, comprising a breathable oxygen delivery system and a medication, the system being fully capable for use in response to symptoms of an attack of a vascular disease; a portable container; wherein the medication is prescribed for a particular user by a physician." (Page 2, paragraph 3, Office action mailed 6/24/03).

Applicant respectfully disagrees. Claim 7 sets out an emergency medical kit,

comprising a breathable oxygen delivery system and a medication for use in response to symptoms of an attack of a vascular disease. Anderson is completely silent with regard to the treatment of a vascular disease.

Claim 14 sets out an the emergency medical kit for use in a pre-hospital setting comprising a breathable oxygen delivery system and a medication for one of, assisting in preventing thrombosis, assisting in inducing arteriolar relaxation, assisting in establishing a cardiac rhythm, and, assisting in diminishing oxygen demand. Anderson is completely silent with regard to providing a medication that is capable of assisting in preventing thrombosis, assisting in inducing arteriolar relaxation, assisting in establishing a cardiac rhythm, and, assisting in diminishing oxygen demand.

Applicant submits that the rejection is improper based on *Verdgaal Bros. v Inion Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single reference."

Applicant submits that each element set forth in claim 7 is not described in Anderson either expressly or inherently. Likewise, Applicant submits that each element set forth in claim 14 is not described in Anderson, expressly or inherently.

Anderson teaches a pulmonary respirator used in the treatment of such diseases as Pulmonary Emphysema, Asthma and Bronchitis and other respiratory diseases in addition to supplying emergency pure oxygen to the heart and airways of the patient, (ABSTRACT). The device taught by Anderson operates in two distinct modes. In a mode called Intermittent Positive Pressure Breathing, (I.P.P.B.), a mixture of air, oxygen and medication is delivery to the patient through a nebulizer assembly 12. In the I.P.P.B. mode, an electric powered blower pushes a medicinal mist into the patient's airways, (Col. 1, lines 35 - 42 and Col. 3, lines 5 - 6). In another operating mode, with the nebulizer assembly 12 removed, a breathing facemask is connected directly to an oxygen valve (27) for delivering only pure oxygen to the patient, (Col. 3, lines 11 - 15).

Anderson neither expressly nor inherently teaches any method or apparatus for

treating a vascular disease of any kind. Anderson neither expressly nor inherently teaches combining breathable oxygen with a medication that has the effect of assisting in preventing thrombosis, assisting in inducing arteriolar relaxation, assisting in establishing a cardiac rhythm, or assisting in diminishing oxygen demand. Anderson is completely silent regarding any apparatus or method for treating a heart attack or a stroke. Anderson is completely silent regarding any apparatus or method for treating obstruction of blood circulation that may cause infarction. Anderson never expressly teaches combining breathable oxygen with a single named medication or even a single named class of medications.

To the extent that Anderson teaches the use of breathable oxygen in an emergency, Applicants have admitted that such treatment for relieving inadequate oxygenation resulting from an attack of a vascular disease is well known, (Page 1, lines 30 – 33). Applicant's specification is clear that the emergency medical kit set out in the claims includes a breathable oxygen supply and a medication that may benefit a person displaying symptoms of, a heart attack, a stroke or other medical condition that may cause infarction, (page 5 lines 11- 14). Not a single teaching of Anderson expressly or inherently teaches or suggests that the Anderson device is for treating a heart attack, stroke or other medical condition that may cause infarction. Anderson fails to expressly or inherently describe each element of claim 7 or of claim 14. Reversal of the Examiners rejection of claims 7 and 14 is hereby respectfully requested.

Claims 2-4, 13, 17, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Mohan. Claim 2-4 stand or fall together.

Applicants submit that the rejection is improper in view of; *In re Royka*, 490 F.2d 891, 180 USPQ 580 (CCPA 1974); "to establish *prima facie* obviousness of a claimed invention all the claim limitations must be taught or suggested by the prior art." Applicants further suggest that the rejection is improper in view of; *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); "The teaching or suggestion to make the claimed

combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure." It is also submitted that the rejection is improper in view of: *In re Millis*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990); "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination."

With respect to claims 2 - 4, which depend from claim 7, the Examiner alleges; "Anderson teaches the emergency medical kit of claim 7," (Page 3, paragraph 7 Office action mailed 6/24/03). Applicant pointed out above that Anderson fails to teach the emergency medical kit set out in claim 7 as alleged by the Examiner because Anderson never teaches or suggests a medical kit that combines a breathable oxygen supply and a medication for use in response to symptoms of an attack of a vascular disease.

Although Mohan teaches, a high-pressure vessel with composite construction that is usable as a lightweight oxygen tank, Mohan also fails to teach or suggest a medical kit that combines a breathable oxygen delivery system and a medication for use in response to symptoms of an attack of a vascular disease, as require by Applicants claim 2 - 4.

Hence, neither Anderson or Mohan alone nor Anderson and Mohan combined, teach all of the claim limitations of claims 2 -4. Accordingly, the Examiner has failed to establish *prima facie* obviousness. Moreover, neither Anderson nor Mohan teach or suggest the desirability for combining a lightweight oxygen tank and a medication for treating an attack of a vascular disease in an emergency medical kit or that such a combination has any reasonable expectation of success. It is further submitted that the first suggestion of the claimed combination is in the Applicants disclosure. Accordingly, reversal of the Examiners rejection of claims 2 - 4 is respectfully requested.

With respect to claim 13, 17, 26 and 27, the Examiner never provides an explanation for the rejection claim 13 and 17 but alleges; with respect to claim 26 and 27, "the emergency medical kit of Anderson/Mohan is fully capable of being used in response to a heart attack or a stroke," (Page 3, paragraph 10, Office Action mailed 6/24/03).

Applicant respectfully disagrees. Claim 13 sets out an emergency medical kit comprising a breathable oxygen delivery system and a medication for use in response to symptoms of an attack of a vascular disease, as soon as the symptoms occur. Claims 26 and 27 further distinguish over claim 13 with the limitation that the vascular disease comprises a heart attack and a stroke respectively. Claim 17 sets out an emergency medical kit for treatment of one of a heart attack and a stroke, upon the onset of symptoms thereof, comprising a breathable oxygen supply and a medication for one of assisting in preventing thrombosis; assisting in inducing arteriolar relaxation; assisting in establishing a cardiac rhythm and assisting in diminishing oxygen demand.

As stated above, Anderson never teaches or suggests an emergency medical kit that includes a breathable oxygen supply and a medication for use in response to symptoms of an attack of a vascular disease, a heart attack, a stroke, or for assisting in preventing thrombosis; assisting in inducing arteriolar relaxation; assisting in establishing a cardiac rhythm or assisting in diminishing oxygen demand. Likewise, Mohan also fails to teach or suggest an emergency medical kit that includes a breathable oxygen supply and a medication for use in response to symptoms of an attack of a vascular disease, a heart attack, a stroke, or for assisting in preventing thrombosis; assisting in inducing arteriolar relaxation; assisting in establishing a cardiac rhythm or assisting in diminishing oxygen demand. Hence, neither Anderson or Mohan alone, nor Anderson and Mohan combined, teach all of the claim limitations of claims 13, 17, 26 and 27. It is respectfully submitted that the Examiner has failed to establish *prima facie* obviousness. Moreover, neither Anderson nor Mohan teach or suggest the desirability for combining a lightweight oxygen tank and a medication for use in response to symptoms of an attack of a vascular disease, a heart attack, a stroke, or for assisting in preventing thrombosis; assisting in inducing arteriolar relaxation; assisting in establishing a cardiac rhythm or assisting in diminishing oxygen demand, or that such a combination has any reasonable expectation of success. It is further submitted that the first suggestion of the claimed combination is in the Applicants disclosure. Accordingly, reversal of the Examiners rejection of claims

13, 17, 26 and 27 is respectfully requested.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Lowell et al. 6292687.

The Examiner alleges; Anderson teaches the medical kit of claim 5, (which depends from claim 7). Applicant respectfully disagrees. Claim 6 sets out an emergency medical kit, comprising a breathable oxygen delivery system and a medication for use in response to symptoms of an attack of a vascular disease, a portable container for housing and carrying the breathable oxygen delivery system and medication and one of a wireless communication device and a loud noise-making device.

Applicants submit that the rejection is improper in view of; *In re Royka*, 490 F.2d 891, 180 USPQ 580 (CCPA 1974); "to establish *prima facie* obviousness of a claimed invention all the claim limitations must be taught or suggested by the prior art." Applicants further suggest that the rejection is improper in view of; *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); "The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure." ." It is also submitted that the rejection is improper in view of: *In re Millis*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990); "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination."

As stated above, Anderson is completely silent with regard to the treatment of a vascular disease so Anderson does not teach the medical kit of claim 5.

Lowell et al. describe a heart dysfunction reader (26) that detects a heart dysfunction occurrence, (Col. 4, lines 62 - 68). Lowell et al. also teach combining the heart dysfunction reader with an alarm (30) for indicating that a heart dysfunction has occurred, (Col. 5, lines 15 - 20). Lowell et al. further teach a system (31, 28) for locating the user and for locating an Automatic External Defibrillator (AED) (33), local to the heart dysfunction reader, for treating a heart dysfunction by defibrillation, (Col. 5, line 58 - Col. 6, line 25). However, Lowell et al. fail to teach or suggest a medical kit that

includes a breathable oxygen supply and a medication for use in response to symptoms of an attack of a vascular disease, as required by claim 6.

Hence, neither Anderson or Lowell et al. alone, nor Anderson and Lowell et al. combined; teach all of the claim limitations of claim 6. It is respectfully submitted that the Examiner has failed to establish "*prima facie* obviousness. Moreover, neither Anderson nor Lowell et al. teach or suggest the desirability for combining a breathable oxygen delivery system with a medication for use in response to symptoms of an attack of a vascular disease, or that such a combination has any reasonable expectation of success. It is further submitted that the first suggestion of the claimed combination is in the Applicants disclosure. Accordingly, reversal of the Examiners rejection of claim 6 is hereby requested.

Claims 8-10, 11 and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Zapol et al. Claims 10 and 29 stand or fall together and claims 9, 11 and 30 stand or fall together.

The Examiner alleges, "Anderson teaches the emergency medical kit of claim 7" and further; "Anderson/Zopal teaches the emergency medical kit of claim 7, wherein the medication is provided in a dosage capable of inducing arteriolar relaxation (col. 5, lines 42- 46) comprising a nitrate, aspirin (acetyalsailicyclic acid), heparin, glycoprotein IIb/II/b inhibitors (col. 1, lines 24-29)."

Applicants submit that the rejection is improper in view of; *In re Royka*, 490 F.2d 891, 180 USPQ 580 (CCPA 1974); "to establish *prima facie* obviousness of a claimed invention all the claim limitations must be taught or suggested by the prior art." Applicants further suggest that the rejection is improper in view of; *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); "The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure." It is also submitted that the rejection is improper in view of: *In re Millis*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990); "The mere fact

that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination."

As stated above with respect to claim 7, Anderson is completely silent with regard to the treatment of a vascular disease, so Anderson does not teach or even suggest the medical kit of claim 7.

Zapol et al. teach methods of treating, inhibiting or preventing vascular diseases, e.g. vascular thrombosis and or arterial restenosis resulting from excessive intimal hyperplasia, (Col. 1, lines 12-16). Each of the methods taught by Zapol et al. requires that a therapeutically effective amount of gaseous nitric oxide, (NO) be inhaled by the mammal being treated, (Col. 1, line 60 - Col. 2 line 4, Col. 4, line 46 and line 63, Col. 5, line 42, Col. 6, lines 13 - Col. 7 line 15). According to Zapol et al., inhaled NO acts as an antithrombotic agent. Zapol et al. further teach combining other antithrombotic agents with inhaled NO, "so that their separate antithrombotic activity is advantageously used to augment the antithrombotic effect(s) of inhaled NO", (Col. 8, line 35).

Applicant can find no suggestion by Zapol et al. to administer breathable oxygen to increase oxygen saturation in the blood for reducing the risk that infarction may result from vascular disease and or arterial restenosis. Moreover, Zapol et al. are completely silent regarding heart attack or stroke. Regarding oxygen, Zapol et al. explicitly states; "It is vital that the NO be obtained and stored as a mixture free of any contaminating $O_2$ or higher oxides of nitrogen, because such higher oxides of nitrogen (which can form by reaction of $O_2$ with NO) are potentially harmful to lung tissue." (Col. 6, line 19-24, Emphasis Added). Zapol et al. also teach that NO may be administered at a concentration of from 0.1 ppm to 300 ppm in air, pure oxygen, or another suitable gas or gas mixture, for as long as needed,"(Col. 6, line 63). Although Zapol et al. suggests mixing NO with pure oxygen, they never suggest that pure oxygen serves any purpose other than to provide a mixing gas for diluting the NO. Moreover, Zapol et al. never suggest that using pure oxygen as a mixing gas, instead of air or another suitable gas, offers any benefit or difference in treating, inhibiting or preventing vascular diseases, e.g. vascular thrombosis

and or arterial restenosis resulting from excessive intimal hyperplasia. Moreover, upon reading Zapol et al., one of ordinary skill might select air instead of oxygen as the preferred mixing gas given the danger to the patient when NO is mixed with $O_2$.

Zapol et al. teach treating, inhibiting or preventing vascular diseases using antithrombotic agents exclusively, with the exception that Zapol et al. also teach administering phosphodieterase inhibitors in conjunction with NO to enhance the affects of the NO. (col. 7, lines 39 - 59). However, Zapol et al. make absolutely no suggestion to administer breathable oxygen to a patient to increase oxygen saturation in the blood either alone or in combination with the antithrombotic agents, (including inhaled NO); to provide the benefit of reducing the risk of infarction caused by reduced blood circulation. Applicant's claims 8, 31 and 32 set out an emergency medical kit comprising a breathable oxygen delivery system and a medication for use in response to symptoms of an attack of a vascular disease. Applicant's claims 9 and 30 set out an emergency medical kit comprising a breathable oxygen delivery system and an anticoagulant. Applicant's claims 10 and 29 set out an emergency medical kit comprising a breathable oxygen delivery system and a cardioprotective agent.

Hence, neither Anderson or Zapol et al. alone, nor Anderson and Zapol et al. combined; teach all of the claim limitations of claims 8 - 10, 11 and 29 - 32, as alleged by the Examiner, and it is respectfully submitted that the Examiner has failed to establish *prima facie* obviousness. It is further submitted that neither Anderson nor Zapol et al. teach or suggest that Applicants claimed combination has any reasonable expectation of success and that the Applicant discloses the only teaching of the claimed combination.

Although Anderson teaches, a breathable oxygen supply, and Zapol et al. teach, medications for use in response to symptoms of an attack of a vascular disease, there is no suggestion in either reference for the desirability of combining breathable oxygen with medications for treating an attack of a vascular disease in an emergency medical kit. Applicant admits that increasing oxygen saturation in heart attack and stokes victims by administering a supply of breathable oxygen, alone, is old in the art. Likewise, Applicant

admits that providing arteriolar relaxations and reduced blood clotting in victims of heart attack or stroke by administering non-prescription medications such as nitroglycerin and aspirin is also old in the art. Accordingly, Zapol et al. adds nothing new to what Applicant has already placed in the record. Reversal of the Examiners rejection of claims 8 - 10, 11 and 29 - 32 is hereby requested.

Claims 12, 28, 29, 33 and 34 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Anderson in view of Duhaylongsod.

The Examiner states that Anderson teaches an emergency medical kit, comprising a breathable oxygen delivery system but fails to teach an antiarrythmic agent, and that it would have been obvious to include the antiarrythmic agent medication taught by Duhaylongsod for precise pacing and control of cardiac contraction during heart attacks or surgery, (Page 5, paragraph 19 Office Action mailed 6/24/03).

Applicant submits that the rejection is improper in view of; *In re Royka*, 490 F.2d 891, 180 USPQ 580 (CCPA 1974); "to establish *prima facie* obviousness of a claimed invention all the claim limitations must be taught or suggested by the prior art." Applicants further suggest that the rejection is improper in view of; *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); "The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure." It is also submitted that the rejection is improper in view of: *In re Millis*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990), "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination."

As stated above, Anderson fails to teach or suggest combining a breathable oxygen supply and a medications for use in response to symptoms of an attack of a vascular disease, in an emergency medical kit. Moreover, Anderson never suggests that such a medical kit is desirable or that the combination has any reasonable expectation of success.

Duhaylongsod teaches techniques for stopping the heart from beating during surgery using an atriovetricular (AV) node blocker in combination with a β-blocker administered in an amount sufficient to reduce the amount of AV node-blocker to induce ventricular asystole, (Col. 5, lines 37 - 46). Duhaylongsod states that when the heart is stopped, blood flow to the rest of the body is provided via a cardiopulmonary bypass, (CPB) and deoxygenated blood is infused with oxygen, (col. 1, lines 38 -50). Duhaylongsod teaches that cardioplegic agents such as a mixture of magnesium sulfate, potassium citrate and neostigmine induce cardioplegia during CPB.

Applicant submits that the entire teaching of Duhaylongsod relates the use of various compounds during cardiac, neuro and vascular surgery. Duhaylongsod teaches administering AV node-blocker in a dosage sufficient for stopping the heart from beating and not in a dosage capable of establishing a cardiac rhythm during an emergency, as set out in Applicants claim 33. Applicant further submits that Duhaylongsod fails to teach or suggest combining a breathable oxygen supply and a medication for use in response to symptoms of an attack of a vascular disease in an emergency medical kit. Moreover, Duhaylongsod never suggests that such an emergency medical kit is desirable or that the claimed combination has any reasonable expectation of success.

Hence, neither Anderson or Duhaylongsod alone, nor Anderson and Duhaylongsod combined; teach all of the claim limitations of claims 12, 28, 29, 33 and 34, as alleged by the Examiner, and it is respectfully submitted that the Examiner has failed to establish *prima facie* obviousness. It is further submitted that neither Anderson nor Duhaylongsod teach or suggest that Applicants claimed combination has any reasonable expectation of success and that the Applicants disclosure is the only teaching of the claimed combination.

Although Anderson teaches, a breathable oxygen supply, and Duhaylongsod teaches administering an antiarrythmic, specifically, an AV node-blocker in a dosage sufficient for stopping the heart from beating, and a β-blocker in an amount sufficient to reduce the amount of AV node-blocker needed to stop the heart from beating, there is no

suggestion in either reference that it would be desirable to combine breathable oxygen with other medications for treating an attack of a vascular disease in an emergency medical kit. Applicant admits that the use of an antiarrythmic such as magnesium, for establishing a cardiac rhythm in heart attack victim is old in the art, (Page 14, lines 11 - 22). Likewise, Applicant admits that the use of a cardio protective agent, such as a β-blocker, for reducing oxygen demand, heart rate and blood pressure, is old in the art, (Page 13, line 25 - Page 14, line 10). Accordingly, Duhaylongsod adds nothing new to what Applicant has already placed in the record. Reversal of the Examiners rejection of claims 8 - 10, 11 and 29 - 32 is hereby requested.

Claims 19, 21, 22 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zapol et al. in view of Kirchgeorge et al. 6327497.

The Examiner alleges; it would have been obvious to combine the treatment methods taught by Zapol et al. with the step of supplying oxygen to a victim using the emergency medical kit taught by Kirchgeorge et al.

Applicant submits that the rejection is improper in view of; *In re Royka*, 490 F.2d 891, 180 USPQ 580 (CCPA 1974); "to establish *prima facie* obviousness of a claimed invention all the claim limitations must be taught or suggested by the prior art." Applicants further suggest that the rejection is improper in view of; *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); "The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure." It is also submitted that the rejection is improper in view of; *In re Millis*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990), "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination."

As stated above, Zapol et al. teach treating, inhibiting or preventing vascular diseases using antithrombotic agents exclusively, with the exception that Zapol et al. also teach administering phosphodieterase inhibitors in conjunction with NO to enhance the

affects of the NO, (col. 7, lines 39 - 59).

The Examiner states that Zapol et al. teach the steps of establishing a risk and predetermining a treatment. Applicant agrees with this characterization, however, every treatment taught by Zapol et al. includes inhaled NO, and Zapol et al. never suggest or suggest any desirability that administering an antithrombotic agent in combination with breathable oxygen is any more beneficial than administering the antithrombotic agent with any other mixing gas, e.g. air. The Examiner further points to (col. 4, lines 46-50), to suggest that Zapol et al. teach the step of teaching the patient how to recognize the symptoms of the serious attack. Applicant disagrees with this characterization. The referenced citation explicitly states; "Mammals and humans in particular, are known to display various signs and symptoms of a thrombosis and may be identified thereby. The recognition of such symptoms is within the skill of medical practitioners, (Emphasis added). Applicant submits that this teaching does not suggest the step of teaching the patient how to recognize the symptoms of the serious attack and how to carry out the treatment, as required by Applicants claims 19, 21 and 25. The Examiner points to (col. 6, lines 56-59) in support that Zapol et al. teach providing a patient with a portable emergency medical kit. Applicant respectfully disagrees with that characterization by the Examiner. The cited reference merely states, "NO may be provided intermittently from an inhaler." There is not suggest that the inhaler is provided to the patient or carried by the patient and there is certainly no suggestion by Zapol et al. that the inhaler be used in an emergency, such as during an attack of a vascular disease. It is respectfully submitted that the Examiner is reading that suggestion into the teachings of Zapol et al. in hindsight, after having had the benefit of reading Applicants disclosure.

Applicant submits that Zapol et al. fails to teach, suggest or suggest a desirability for the steps of providing a patient with an emergency medical kit that includes breathable oxygen and a medication for assisting in preventing thrombosis as required by claims 21, 22 and 25. Zapol et al. also fails to teach, suggest or suggest a desirability for the step of providing a patient with an emergency medical kit that includes breathable oxygen alone,

as required by claim 19, or for the steps of providing a patient with an emergency medical kit that includes breathable oxygen, teaching the patient how to recognize the symptoms of a serious attack, and teaching the patient how to carry out the treatment upon the onset of symptoms, as required by claims 19, 21 and 25.

Kirchgeorge et al. teach a medical diagnosis and therapy system with combined uses of emergency cardiac defibrillation and pulmonary oxygen administration, (ABSTRACT). The kit comprises a unitary case, or housing (1), containing a small-sized emergency oxygen unit or gas dispensing device (70) with an oximeter (103), a pulse display (116) and electrode lead or sensor (107). The kit may also include an Automatic External Defibrillator (AED) (75), a user voice prompt system (112) and one or more display devices, speakers and electronics, (Figure 4 and col. 3, line 15 - 20). It is also noted that the kit of Kirchgeorge et al. is for use by a first responder or other emergency medical personnel, (col. 1 line 37, col. 2, line 5). However, Kirchgeorge et al. are completely silent with regard to providing breathable oxygen in combination with another medication of any kind. Moreover, Kirchgeorge et al. are completely silent with regard to providing a person or patient with a medical kit or with teaching or training a patient to use the medical kit or how to carry out a treatment.

Applicant submits that Kirchgeorge et al. fail to teach, suggest or suggest any desirability for the step of providing the patient with a portable emergency medical kit for carrying out the treatment upon the onset of symptoms before the patient can be treated by a medical professional as required by each of claims 19, 21, 22 and 25. Kirchgeorge et al. also fail to teach, suggest, or suggest any desirability for, the step providing the person susceptible to the serious attack with a medication for use in response to symptoms of the serious attack, and wherein the medication is also included in the emergency medical kit, as required by Applicants claims 21, 22 and 25.

Hence, neither al. or Kirchgeorge et al. alone, nor Zapol et al. and Kirchgeorge et al., in combination; teach all of the claim limitations of claims 19, 21, 22 and 25, as alleged by the Examiner, and it is respectfully submitted that the Examiner has failed to

establish *prima facie* obviousness. Specifically neither reference teaches or suggests the step of providing a person susceptible to a serious attack of a vascular disease with an emergency medical kit that includes a breathable oxygen delivery system. It is further submitted that neither Zapol et al. or Kirchgeorge et al. alone, nor Zapol et al. and Kirchgeorge et al. in combination, teach or suggest that providing a person susceptible to a serious attack of a vascular disease with an emergency medical kit that includes a breathable oxygen delivery system, has any reasonable expectation of success. It is further submitted that Applicants disclosure provides the only teaching of providing a person susceptible to a serious attack of a vascular disease with an emergency medical kit that includes a breathable oxygen delivery system. Reversal of the Examiners rejection of claims 19, 21, 22 and 25 is hereby requested

Applicant respectfully submits that the claims pending herein set out a combination of features that is not taught or suggested by any of the prior art of record. Moreover, it is submitted that the prior art of record fails to suggest any desirability of the claimed combination of features nor does the prior art of record offer any reasonable expectation that the claimed combination of features would be successful for preventing death or permanent tissue damage in a patient suffering from a serious attack of a vascular disease, which restricts blood circulation. The invention claimed herein addresses the need for a simple low cost portable emergency medical kit that is given or prescribed to the user, that is customized to the particular needs of the user, and that could save the life or reduce the risk of permanent tissue damage of a victim of a serious attack of a vascular disease such as a heart attack, stroke or other life threatening condition caused by vascular disease or trauma in a person that has a known susceptibility to such an attack. An emergency medical kit including breathable oxygen and a medication or combination of medications for administering treatment and especially for self administering treatment for a serious attack of a vascular disease during the period between the onset of symptoms and the arrival of a trained medical professional can save a persons life, yet the features set out in Applicants claims are nowhere suggested in the

cited prior art nor is there a suggestion in the prior art of record that such a medical kit would be desirable or could be successful.

If the Examiner or the Board of Patent Judges feel that any further discussion of the invention would be helpful, applicant's representative is available by telephone at (781) 541-6579, by Fax at (781) 541-6747 or by email, kelley.ima@rcn.com, and earnestly solicits such discussion.

Respectively submitted,

Applicants

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## 9) APPENDIX: PENDING CLAIMS

1. (cancelled)

2. The emergency medical kit of claim 7 wherein the breathable oxygen delivery system comprises a portable oxygen tank for storing oxygen under high pressure and wherein the portable oxygen tank comprises a composite material over wrapped onto a gas impermeable inner vessel.

3. The emergency medical kit of claim 2 wherein the breathable oxygen delivery system comprises a portable oxygen tank having an empty weight of less than 5.0 pounds.

4. The emergency medical kit of claim 2 wherein the breathable oxygen delivery system comprises a portable oxygen tank having an empty weight of less than 2.0 pounds.

5. The emergency medical kit of claim 7 further comprising a portable container for housing and carrying the breathable oxygen delivery system and the medication.

6. The emergency medical kit of claim 5 further comprising one of a wireless communication device and a loud noise-making device.

7. An emergency medical kit, comprising a breathable oxygen delivery system and a medication for use in response to symptoms of an attack of a vascular disease.

8. The emergency medical kit of claim 7 wherein the medication is prescribed for a particular user by a physician and wherein the user has a known susceptibility to an attack of the vascular disease.

9. An emergency medical kit, comprising a breathable oxygen delivery system and an anticoagulant for use in response to symptoms of a particular serious illness as soon as the symptoms occur.

10. The emergency medical kit of claim 29 wherein the cardioprotetcive agent comprises one of a nitrate, a beta blocker and an ACE inhibitor.

11. The emergency medical kit of claim 9 wherein the anticoagulant comprises one of acetylsalicyclic acid, clopidogrel, heparin and glycoprotein IIb/III/b inhibitors.

12. The emergency medical kit of claim 28 wherein the antiarrythmic comprises magnesium.

13. An emergency medical kit, comprising:

- a breathable oxygen delivery system and a medication for use in response to symptoms of an attack of a vascular disease as soon as the symptoms occur and wherein the breathable oxygen delivery system comprises:
- an oxygen storage tank having at least a 50 cubic inch internal storage capacity, an oxygen storage operating pressure range of between 100 and 4000 PSI and an empty weight of less than 5.0 pounds;
- a regulator valve attached to the oxygen storage tank for receiving oxygen from

the tank at an inlet pressure of between 100 - 4000 PSI and delivering oxygen at an outlet pressure range of less than 50 PSI;

- an oxygen delivery tube having an inlet end attached to the regulator valve for receiving oxygen at the pressure of less than 50 PSI and an outlet end; and,
- a user oxygen delivery device attached to said delivery tube outlet end for delivering a supply of breathable oxygen to a user.

14. An emergency medical kit for use in a pre-hospital setting comprising:

- a breathable oxygen delivery system and a medication for one of;
- assisting in preventing thrombosis;
- assisting in inducing arteriolar relaxation
- assisting in establishing a cardiac rhythm; and,
- assisting in diminishing oxygen demand.

15. The emergency medical kit of claim 14 wherein the medication is prescribed by a physician for one of a known condition and a susceptibility to a known condition.

16. A medical emergency kit according to claim 15 wherein the breathable oxygen supply is prescribed by a physician in a preset condition to deliver oxygen at at least one of a predetermined rate and a predetermined pressure.

17. An emergency medical kit for treatment of one of a heart attack and a stroke upon the onset of symptoms thereof comprising:

- a breathable oxygen supply having;

- an oxygen storage tank having at least a 50 cubic inch internal storage capacity, an oxygen storage operating pressure range of between 100 and 4000 PSI and an empty weight of less than 5.0 pounds;
- a regulator valve attached to the oxygen storage tank for receiving oxygen from the tank at an inlet pressure of between 100 - 4000 PSI and delivering oxygen at an outlet pressure range of less than 50 PSI;
- an oxygen delivery tube having an inlet end attached to the regulator valve for receiving oxygen at the pressure of less than 50 PSI and an outlet end; and,
- a user oxygen delivery device attached to said delivery tube outlet end for delivering a supply of breathable oxygen to a user;
- a medication for one of assisting in preventing thrombosis; assisting in inducing arteriolar relaxation; assisting in establishing a cardiac rhythm and assisting in diminishing oxygen demand; and,
- a portable container for storing and transporting the breathable oxygen supply in a convenient manner.

18. (cancelled)

19. A method for treating a serious attack of a vascular disease immediately upon the onset of one or more symptoms of the attack comprising the steps of:

- establishing a risk that a patient may suffer an unexpected attack of the vascular disease;
- predetermining a treatment for prolonging the patient's life and reducing a risk of permanent tissue damage to the patient in the event that the attack occurs;
- providing the patient with a portable emergency medical kit for carrying out the

treatment upon the onset of the symptoms before the patient can be treated by a medical professional, said portable emergency medical kit including a supply of breathable oxygen; and,

- teaching the patient how to recognize the symptoms of the serious attack and how to carry out the treatment upon the onset of the symptoms.

20. (cancelled)

21. The method of claim 19 wherein the step of predetermining a treatment further comprises the step of providing a medication in the portable emergency kit for one of:

- assisting in preventing thrombosis;
- assisting in inducing arteriolar relaxation;
- assisting in establishing a cardiac rhythm; and,
- assisting in diminishing oxygen demand.

22. A method for treating a serious attack of a vascular disease comprising the steps of;

- providing a person susceptible to the serious attack with a breathable oxygen delivery system;
- providing the person susceptible to the serious attack with a medication for use in response to symptoms of the serious attack as soon as the symptoms occur; and,
- wherein said medication is for one of assisting in preventing thrombosis, assisting in inducing arterial relaxation, assisting in establishing a cardiac rhythm, and assisting in diminishing oxygen demand.

23. (cancelled)

24. (cancelled)

25. A method for treating an unexpected attack from a vascular disease comprising the steps of;

- providing a person with a known susceptibility to the vascular disease with a breathable oxygen delivery system and a medication for one of assisting in preventing thrombosis; assisting in inducing arteriolar relaxation; assisting in establishing a cardiac rhythm; and, assisting in diminishing oxygen demand;
- providing the breathable oxygen delivery system and the medication in a container for easy portability by the person; and,
- instructing the person in the use of the breathable oxygen and the medication in response to predefined symptoms of the unexpected attack from the vascular disease.

26. The emergency medical kit of claim 13 wherein the attack of a vascular disease comprises a heart attack.

27. The emergency medical kit of claim 13 wherein the attack of a vascular disease comprises a stroke.

28. An emergency medical kit comprising a breathable oxygen delivery system and an

antiarrythmic agent for use in response to symptoms of a particular serious illness as soon as the symptoms occur.

29. An emergency medical kit, comprising a breathable oxygen delivery system and a cardioprotective agent for use in response to symptoms of a particular serious illness as soon as the symptoms occur.

30. The emergency medical kit of claim 9 wherein the anticoagulant comprises acetylsalicyclic acid.

31. The emergency medical kit of claim 7 wherein the medication is provided in a dosage capable of preventing thrombosis.

32. The emergency medical kit of claim 7 wherein the medication is provided in a dosage capable of inducing arteriolar relaxation.

33. The emergency medical kit of claim 7 wherein the medication is provided in a dosage capable of establishing a cardiac rhythm.

34. The emergency medical kit of claim 7 wherein the medication is provided in a dosage capable of diminishing oxygen demand.